510K Supplement
K134017/S001
GIGALaser 1801
April 1, 2014

Exhibit B. 510(k) Summary (as per 21 CFR 807.92)

MAY 0 2 2014

I. GENERAL INFORMATION

Device Generic Name:	Infrared Low Level Laser System
Trade Name:	**GIGA**Laser 1801
Device Classification:	Class II, Performance Standards – 21CFR Part 890.5500 – Infrared Lamp, Non-Heating
Product Code:	ILY
Applicant Name and Address:	PowerMedic ApS Gasvaerksvej 8 DK-4300 Holbaek Denmark Tel: +45 5944 0832
Key Contact:	Arne Grinsted
510(k) Number:	K134017

II. Device Description

The **GIGA**Laser 1801 is a non-invasive, low level therapeutic laser lamp. The control unit contains the power supply and the user interface panel. The IR laser lamp is placed on a folding arm which is attached to the base unit. The interface panel consists of three buttons for 'STOP', 'START' AND 'PAUSE' and there are 6 buttons for the 6 different pre-programmed treatment programs labeled 1 – 6. The buttons light up when selected. A LED segment tells the user the time the treatment has run. The **GIGAL**aser 1801 is also equipped with a main key power switch and an emergency stop. The GigaLaser is a medical device, which is delivered with a user and therapy manual and a complete labeling for the user.

Principles of operation:
The **GIGA**Laser 1801 is a stationary medical device. The device consists of a base mechanical unit that holds a control unit and an extension arm that holds the light panel including the laser diodes. The user selects the desired therapy program, thereby selecting output power level and exposure time, using the 6 different touch buttons, labeled 1-6, located on the top of the control panel. After the user has selected the therapy program the user starts

the program by pressing the 'PLAY' touch button also located on the top of the control unit together with the 'PAUSE' and the 'STOP' button.

After the user has activated the 'PLAY' button the therapy program will run until, if not stopped manually by the user then stops automatically when the treatment is over. On the back of the control unit there are the emergency STOP button, the mains plug in, the interconnection switch and the connection output plug for the light panel.

Typical use of product:
The **GIGA**Laser 1801 is typically used to utilize infrared diodes to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and the temporary relaxation of muscle. The **GIGA**Laser 1801 is placed directly above the skin to provide heating. The area is treated for the fixed exposure time.

III. Indications for Use

GIGALaser 1801 is intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and for the temporary relaxation of muscles.

IV. Predicate Devices

The **GIGA**Laser 1801 is substantially equivalent to other infrared therapeutic devices that are currently in commercial distribution. Following is a list of the predicate devices cleared by the FDA via 510K Notification process.

510(k) Number	Predicate Device Name	Manufacturer
K070516	PowerLaser	PowerMedic ApS
K030426	Omnilux Revive	Photo Therapeutics Limited

V. Summary of the Technical Characteristics of the GigaLaser as Related to the Referenced Predicate Devices.

The **GIGA**Laser 1801 is a non-heating infrared lamps as defined in 21 CFR 890.5500. The **GIGA**Laser 1801 has the same technological and functional characteristics as the aforementioned predicate devices in that all utilize infrared laser diodes and visible LED diodes for the purpose of providing adjunctive therapy treatments.

VI. Bench Testing

Electrical safety and functional performance testing was conducted on the GigaLaser demonstrating that the device is compliant with FDA recognized consensus standards. These standards include, but are not limited to, the following international standards:

EN 60601-1: 2006- Medical Electrical Equipment, Part 1, General Requirements for Safety

EN 60601-1-2:2001/A1:2006 - Medical Electrical Equipment, General Requirement for Safety. Electromagnetic Compatibility

EN 60601-2-22:1997 – Medical Laser Equipment

CE Marking Classification: Medical Device Directive 93/42/EEC

VII. Clinical Testing

The use of light energy to generate heat for therapeutic use has been well documented and is generally accepted alternative treatment modality for the temporary relief of pain and tissue repair.

The **GIGA**Laser 1801 is capable of achieving therapeutic heat temperature range of 40 - 45 degrees centigrade as accepted by the FDA. An increase in topical heating of the tissue level by at least 5° centigrade was reached within one (1) minute demonstrated in the clinical testing conducted. The therapeutic temperature range was maintained for at least ten (10) minutes.

The temperature versus time measurements was conducted on 4 subjects at various physical locations, i.e., arm, leg and shoulder. The pre-exposed topical skin temperature ranged from 36 to 39 degrees centigrade. These data demonstrate the **GIGA**Laser 1801 meets the generally accepted topical temperature range for therapeutic heat of 40 – 45 degrees centigrade during the recommended treatment time of 10 minutes.

VIII. Conclusions

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device may have the same intended use and different technological characteristics if they can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regards its safety and effectiveness as compared to the predicate device.

The **GIGA**Laser 1801 has the same intended uses, with similar technical, functional and performance characteristics as the predicate devices listed above. The GigaLaser is designed to comply with applicable performance standards promulgated by Federal Food and Drug Administration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2014

PowerMedic ApS
% Ms. Joyce Heinrich
Texas Applied Biomedical Services
12101 Cullen Boulevard, Suite A
Houston, Texas 77047

Re: K134017
Trade/Device Name: GIGALaser 1801
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: April 1, 2014
Received: April 3, 2014

Dear. Ms. Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
2014.05.02 17:58:08 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K134017

Device Name
GIGALaser 1801

Indications for Use *(Describe)*
GIGALaser 1801 is intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and for the temporary relaxation of muscles.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.05.02 16:48:19 -04'00'

For BSA